

### **Remarks**

Claims 1, 2, 4-9, 11, 12 and 14-16, 17-19 are currently pending in the application.

Applicant gratefully acknowledges the Office Action's indication that claims 1, 2, 4-9, 11, 12, and 14-16 are allowable. Applicants have amended claims 17-18 in order to expedite the issuance of the claims. The amendments are made without prejudice, do not constitute amendments to overcome any prior art rejection, and do not present any new matter. Support for the newly added claims can be found throughout the specification as filed.

### **Priority**

The Office Action accorded an effective priority date of January 12, 2000 to claims 1, 2, 4-9, 11, 12 and 14-16. The Office Action, however, accorded an effective priority date of January 12, 2001, the filing date of the present application, to claims 17-19. Applicants do not acquiesce to this priority date determination for these claims or the Office Action's reasoning supporting this priority date determination. However, in view of Applicant's amendment to claims 17 and 18, a priority determination is not necessary or required for claims 17-19.

### **Discussion of the 35 U.S.C. § 103(a) Rejections**

Claims 17 stands rejected under 35 U.S.C. § 103(a) as being obvious over Roninson *et al.* (U.S. 2004/0058320) ("Roninson application").

An analysis for obviousness requires a determination of the scope and content of the prior art, the differences between the prior art and the claims at issue must be ascertained, and the level of ordinary skill in the pertinent art must be resolved. A claim can only be rendered

obvious if each and every element as set forth in the claim is found in the prior art, or such limitation would have been obvious to one of skill in the art.

Claim 17 is directed in part to the use of p27 expression, p16 expression, or both p27 and p16 expression, as biological markers. The Office Action's citation of the Roninson application does not mention or allege that the Roninson application teaches or discloses either p27 expression or p16 expression as biological markers. In fact, Roninson contains no mention of p27, and the only reference to p16 was to indicate that the cell line used in Example 2 does not express p16. *See* Roninson, ¶¶ 65 & 70. Without the citation of any reference that discloses the use of p27 expression or p16 expression as biological markers, Applicant respectfully contends that claim 17 is not obvious in view Roninson. Applicant therefore respectfully requests withdrawal of this § 103 obviousness rejection and requests reconsideration of the claim.

Claims 18 and 19 stand rejected under 35 U.S.C. § 103(a) as being obvious over the Roninson application in view of Bacus (U.S. 4,741,043). Applicant respectfully traverses this rejection.

Claims 18-19 are directed in part to the use of p27 expression, p16 expression, or both p27 and p16 expression, as biological markers. The Office Action's citation of the Roninson application does not mention or allege that the Roninson application teaches or discloses either p27 expression or p16 expression as biological markers. In fact, Roninson contains no mention of p27, and the only reference to p16 was to indicate that the cell line used in Example 2 does not express p16. *See* Roninson, ¶¶ 65 & 70. Further, the Office Action only cites to Bacus as teaching the determination of optical density by image analysis, and does not allege that Bacus teaches or discloses the use of p27 expression or p16 expression as biological markers. Without

the citation of any reference that discloses the use of p27 expression or p16 expression as biological markers, Applicant respectfully contends that claim 18-19 is not obvious in view Roninson and/or Bacus. Applicant therefore respectfully requests withdrawal of this § 103 obviousness rejection and requests reconsideration of the claim.

**Conclusion**

In view of the above amendments and remarks, the application is considered to be in good and proper form for allowance and the Examiner is respectfully requested to pass this application to issue. If there are any questions or comments regarding this Response or application, the Examiner is encouraged to contact the undersigned attorney as indicated below.

Respectfully Submitted,

Date: December 2, 2009

/Andrew W. Williams/  
Andrew W. Williams  
Reg. No. 48,644